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PTO/SB/21 (09-04)
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TRANSMITTAL FORM (to be used for all correspondence after initial filing)	Application Number	10/823,426	
	Filing Date	April 12, 2004	
	First Named Inventor	Naweed MUHAMMAD	
	Art Unit	1614	
	Examiner Name	Not Yet Assigned	
Total Number of Pages in This Submission	14 pages + 90 refs.	Attorney Docket Number	524522001300

ENCLOSURES (Check all that apply)		
<input type="checkbox"/> Fee Transmittal Form <input type="checkbox"/> Fee Attached <input type="checkbox"/> Amendment/Reply <input type="checkbox"/> After Final <input type="checkbox"/> Affidavits/declaration(s) <input type="checkbox"/> Extension of Time Request <input type="checkbox"/> Express Abandonment Request <input checked="" type="checkbox"/> Information Disclosure Statement - 3 pages <input type="checkbox"/> Certified Copy of Priority Document(s) <input type="checkbox"/> Reply to Missing Parts/ Incomplete Application <input type="checkbox"/> Reply to Missing Parts under 37 CFR 1.52 or 1.53	<input type="checkbox"/> Drawing(s) <input type="checkbox"/> Licensing-related Papers <input type="checkbox"/> Petition <input type="checkbox"/> Petition to Convert to a Provisional Application <input type="checkbox"/> Power of Attorney, Revocation Change of Correspondence Address <input type="checkbox"/> Terminal Disclaimer <input type="checkbox"/> Request for Refund <input type="checkbox"/> CD, Number of CD(s) _____ <input type="checkbox"/> Landscape Table on CD	<input type="checkbox"/> After Allowance Communication to TC <input type="checkbox"/> Appeal Communication to Board of Appeals and Interferences <input type="checkbox"/> Appeal Communication to TC (Appeal Notice, Brief, Reply Brief) <input type="checkbox"/> Proprietary Information <input type="checkbox"/> Status Letter <input checked="" type="checkbox"/> Other Enclosure(s) (please identify below): Form PTO/SB/08a/b + copy - 10 pages Ninety (90) references Return Receipt Postcard
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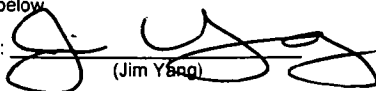
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Date	June 2, 2005	Reg. No.	47,777

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(Jim Yang)

Patent

Docket No. 524522001300

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Naweed MUHAMMAD et al.

Serial No.: 10/823,426

Filing Date: April 12, 2004

For: METHODS AND COMPOSITIONS FOR
ADMINISTRATION OF TRPV1
AGONISTS



Examiner: Not Yet Assigned

Group Art Unit: 1614

**INFORMATION DISCLOSURE
STATEMENT UNDER 37 C.F.R. § 1.97 & 1.98**

MS Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

Dear Sir:

Pursuant to 37 C.F.R. §1.97 and § 1.98, Applicants submit for consideration in the above-identified application the documents listed on the attached Form PTO/SB/08a/b. Copies of foreign documents and non-patent literature are submitted herewith. The Examiner is requested to make these documents of record.



This Information Disclosure Statement is submitted:

- ☐ With the application; accordingly, no fee or separate requirements are required.
- ☐ Before the mailing of a first Office Action after the filing of a Request for Continued Examination under § 1.114. However, if applicable, a certification under 37 C.F.R. § 1.97 (e)(1) has been provided.
- ☒ Within three months of the application filing date or before mailing of a first Office Action on the merits; accordingly, no fee or separate requirements are required. However, if applicable, a certification under 37 C.F.R. § 1.97 (e)(1) has been provided.
- ☐ After receipt of a first Office Action on the merits but before mailing of a final Office Action or Notice of Allowance.
 - ☐ A fee is required. A check in the amount of __ is enclosed.
 - ☐ A fee is required. Accordingly, a Fee Transmittal form (PTO/SB/17) is attached to this submission in duplicate.
 - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above; accordingly; no fee is believed to be due.
- ☐ After mailing of a final Office Action or Notice of Allowance, but before payment of the issue fee.
 - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above and a check in the amount of __ is enclosed.
 - ☐ A Certification under 37 C.F.R. § 1.97(e) is provided above and a Fee Transmittal form (PTO/SB/17 is attached to this submission in duplicate.)

Applicants would appreciate the Examiner initialing and returning the Form PTO/SB/08a/b, indicating that the information has been considered and made of record herein.


The information contained in this Information Disclosure Statement under 37 C.F.R. § 1.97 and § 1.98 is not to be construed as a representation that: (i) a complete search has been made; (ii) additional information material to the examination of this application does not exist;

(iii) the information, protocols, results and the like reported by third parties are accurate or enabling;
or (iv) the above information constitutes prior art to the subject invention.

In the unlikely event that the transmittal form is separated from this document and the Patent and Trademark Office determines that an extension and/or other relief (such as payment of a fee under 37 C.F.R. § 1.17 (p)) is required, Applicants petition for any required relief including extensions of time and authorize the Commissioner to charge the cost of such petition and/or other fees due in connection with the filing of this document to **Deposit Account No. 03-1952** referencing 524522001300.

Dated: June 2, 2005

Respectfully submitted,

By 
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ALTERNATIVE TO PTO/SB/08a/b (06-03)

Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Application Number	10/823,426
				Filing Date	April 12, 2004
				First Named Inventor	Naweed MUHAMMAD
				Art Unit	1614
				Examiner Name	Not Yet Assigned
Sheet	1	of	5	Attorney Docket Number	524522001300

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. ¹	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number-Kind Code ² (if known)			
/M.Y./ ↓	1.	US-2002/0058048-A1	05-16-2002	Tamura et al.	
	2.	US-2003/0104040-A1	06-05-2003	Kirby et al.	
	3.	US-2003/0104085-A1	06-05-2003	Yeomans	
	4.	US-2005/0084520-A1	04-21-2005	Bernstein	
	5.	US-4,313,958	02-02-1982	LaHann	
	6.	US-4,493,848	01-15-1985	LaHann et al.	
	7.	US-4,532,139	07-30-1985	Janusz et al.	
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	16.	US-5,716,643-A	02-10-1998	Yen	
	17.	US-5,762,963-A	06-09-1998	Byas-Smith	
	18.	US-5,879,696-A	03-09-1999	Blumberg	
	19.	US-5,962,532-A	10-05-1999	Campbell et al.	
	20.	US-6,013,270-A	01-11-2000	Hargraves et al.	
	21.	US-6,103,266-A	08-15-2000	Tapolsky et al.	
	22.	US-6,239,180-B1	05-29-2001	Robbins	
	23.	US-6,248,788-B1	06-19-2001	Robbins et al.	
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	28.	US-6,638,981-B2	10-28-2003	Williams et al.	

FOREIGN PATENT DOCUMENTS							
Examiner Initials*	Cite No. ¹	Foreign Patent Document	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶	
		Country Code ³ -Number ⁴ -Kind Code ⁵ (if known)					
M.Y.	29.	EP-0 225 848-A2	06-16-1987	Warner-Lambert Co.			
	30.	EP-0 347 000-A2	12-20-1989	The Procter & Gamble Co.			
↓	31.	WO-92/09285-A1	06-11-1992	The Procter & Gamble Company			
	32.	WO-98/03641-A1	01-29-1998	Crandall			
	33.	WO-00/09117-A1	02-24-2000	Edko Trading and Representation Co. Ltd.			
	34.	WO-00/50007-A1	08-31-2000	Lipocine, Inc.			
	35.	WO-00/50387-A1	08-31-2000	Pacific Corporation			
	36.	WO-00/59475-A1	10-12-2000	Lipocine, Inc.			
	37.	WO-00/67730-A1	11-16-2000	U.S. Dermatologics, Inc.			
	38.	WO-2004/021990-A2, A3	03-18-2004	Neurogesx, Inc.			
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	M.Y.	40.	WO-2004/092122-A2	10-28-2004	Alcorx Pharmaceuticals		

Examiner Signature	/Micah Paul Young/ (02/17/2009)	Date Considered	02/17/2009
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pa- 982742

Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Application Number	10/823,426
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				First Named Inventor	Naweed MUHAMMAD
				Art Unit	1614
				Examiner Name	Not Yet Assigned
Sheet	2	of	5	Attorney Docket Number	524522001300

/M.Y./	41.	WO-2005/009510-A2	02-03-2005	The Regents of the University of California	
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*EXAMINER: Initial if information considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant. ¹ Applicant's unique citation designation number (optional). ² See Kinds Codes of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

NON PATENT LITERATURE DOCUMENTS				
Examiner Initials	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.		T ²
/M.Y./	42.	Anonymous (July 2004). "Adding Value with ATD Technology," <i>Antares Pharma AG</i> , pp. 1-38.		
/M.Y./	43.	Anonymous (2004). "I Have Vulvodynia-What Do I Need to Know: A Self-Help Guide for Women Diagnosed with Vulvodynia," <i>National Vulvodynia Association Pamphlet</i> 12 pages.		
/M.Y./	44.	Asbill, C.S. et al. (2000). "Enhancement of Transdermal Drug Delivery: Chemical and Physical Approaches," <i>Crit. Rev. Ther. Drug Carrier Syst.</i> 17(6):621-658.		
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/M.Y./	58.	Chancellor, M.B. et al. (July 1999). "Intravesical Capsaicin and Resiniferatoxin Therapy: Spicing up the Ways to Treat the Overactive Bladder," <i>J. Urol.</i> 162:3-11.		

Examiner Signature	/Micah Paul Young/ (02/17/2009)	Date Considered	02/17/2009
pa- 982742			

Substitute for form 1449/PTO				Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(Use as many sheets as necessary)</i>				Application Number	10/823,426
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				Art Unit	1614
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Sheet	3	of	5	Attorney Docket Number	524522001300

/M.Y./	59.	Chattaraj, S.C. et al. (1995). "Chemical Penetration Enhancers" Table 1 In "Penetration Enhances Classification" Chapter 1.2 In <u>Percutaneous Penetration Enhancers</u> Smith, E.W. et al. eds. CRC Press: Boca Raton, Florida pp. 7-8.
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/M.Y./	61.	Dray, A. et al. (1991). "Systemic Capsaicin and Olvanil Reduce the Acute Algogenic and the Late Inflammatory Phase Following Formalin Injection Into Rodent Paw," <i>Pain</i> 47:79-83.
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/M.Y./	82.	Kobayashi, Y. (May 2003). "The Nociceptive and Anti-Nociceptive Effects of Evodiamine from Fruits of <i>Evodia rutaecarpa</i> in Mice," <i>Planta Med</i> 69:425-428.

Examiner Signature	/Micah Paul Young/ (02/17/2009)	Date Considered	02/17/2009
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/M.Y./	83.	Kobayashi, Y. et al. (2000). "The Bronchoconstrictive Action of Evodiamine, an Indoloquinazoline Alkaloid Isolated From the Fruits of <i>Evodia rutaecarpa</i> , on Guinea-Pig Isolated Bronchus: Possible Involvement on Vanilloid Receptors," <i>Planta Med</i> 66:526-530.	
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/M.Y./	86.	Montell, C. et al. (February 2002). "A Unified Nomenclature for the Superfamily of TRP Cation Channels," <i>Mol. Cell.</i> 9:229-231.	
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/M.Y./	94.	Saper, J.R. et al. (June 2002). "Intranasal Civamide for the treatment of Episodic Cluster Headaches," <i>Arch. Neurol.</i> 59:990-994.	
/M.Y./	95.	Shifflet, M.J. et al. (2002). "Development of Analytical Methods to Accurately and Precisely Determine Residual Active Pharmaceutical Ingredients and Cleaning Agents on Pharmaceutical Surfaces," <i>American Pharmaceutical Review</i> pp. 35-40.	
/M.Y./	96.	Siao, P. et al. (2003). "Quantitative Sensory Testing," <i>Phys. Med. Rehabil. Clin. N. Am.</i> 14:261-286.	
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Examiner Signature	/Micah Paul Young/ (02/17/2009)	Date Considered	02/17/2009
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Substitute for form 1449/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (Use as many sheets as necessary)				Complete if Known	
				Application Number	10/823,426
				Filing Date	April 12, 2004
				First Named Inventor	Naweed MUHAMMAD
				Art Unit	1614
				Examiner Name	Not Yet Assigned
Sheet	5	of	5	Attorney Docket Number	524522001300

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*EXAMINER: Initial if information considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional). ²Applicant is to place a check mark here if English language Translation is attached.

Examiner Signature	/Micah Paul Young/ (02/17/2009)	Date Considered	02/17/2009
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